Lyme Disease
Convention and Controversies

Richard A. Jacobs, M.D., PhD.

NO DISCLOSURES
Willie Burgdorfer, Ph.D. (1925-2014)
RM Lab in Hamilton, MT

Polly Murray who first reported an outbreak of arthritis in 12 children from Old Lyme, CT in 1975—the first description of what would become to be known as Lyme disease.

Author of “The Widening Circle: A Lyme disease Pioneer Tells Her Story”
Dr. Allen Steere, who at the time was a Rheumatology Fellow at Yale University, was sent to investigate the outbreak of arthritis. In 1977 published a paper on Lyme Arthritis. (Arthritis and Rheumatism 1977;20:7)

Outline

• Clinical manifestations
• Diagnosis
• Therapy
• Prevention
• Controversies
Case

• A 35 yo woman is being evaluated for a 6 month h/o fatigue, arthralgias without arthritis and memory loss manifest as word-finding difficulties and forgetfulness. The work-up has been thorough but frustrating for both the provider and the patient because answers have not been forthcoming. Finally, after an exhaustive internet search, she requests that Lyme disease serologies be performed. The provider reluctantly agrees.

Case

• Serologies
  – CDC recommends 2-stage testing
    • Screening ELISA or IFA—very sensitive but not specific
      – If negative—>no further testing
      – If positive/equivocal—>confirmatory test
    • Confirmatory Western blot
      – IgM
      – IgG
Case

- Serologies return:
  - Screening test is equivocal
  - Confirmatory Western blot is IgM (+) and IgG (-)

Questions

- How do you interpret the serologies?
- Does she have Lyme disease?
Definition

Lyme disease is a bacterial infection caused primarily by the spirochete Borrelia burgdorferi in the US (less commonly by B. mayonii in the upper mid-West) and B. afzelii, and garinii in Europe and Asia (less commonly by B. burgdorferi and rarely by B. spielmanii and B. bavariensis) and is transmitted to humans by the bite of infected Ixodes ricinus complex deer tick.

The clinical manifestations can be complex but affect primarily the skin, joints, nervous system and heart.

“Tick Biology 101”
“Tick Biology 101”

• Hard ticks (over 700 species)
  – Ixodes ricinus complex
  – Different geographic distributions
    • Northeastern and upper midwestern states
      – Ixodes scapularis (also called Ixodes dammini)
    • Western states—Ixodes pacificus
    • Europe—Ixodes ricinus
    • Asia—Ixodes persulcatus

• Soft ticks (over 150 species)

“Tick Biology 101” (continued)

• Three stages:
  – Larval—feeds from August to September on white-footed mouse
  – Nymphal★★—feeds from May through July on white-footed mouse
  – Adult—feeds on larger mammals, especially deer in the spring and fall

★★ Nymph primarily responsible for disease transmission
Most clinical cases occur in the summer months
Tick Biology (continued)

Ixodes scapularis (Blacklegged ticks or Deer ticks)

- Larva
- Nymph
- Adult Male
- Adult Female

Tick Biology (continued)
Tick Biology (continued)

Engorged Tick
Clinical Manifestations

• Early Localized Disease
  – Usually occurs 7-10 days after the bite
  – Range 3-30 days

• Early Disseminated Disease
  – Weeks to months after the bite

• Late Disease
  – Months to years after exposure

Early Localized Disease

• Erythema Migrans
  – Seen in 70%-80% of cases
  – Begins 7-10 days after the bite (3-30 day range)
  – Starts at the site of the tick bite
  – Slowly expanding (over several days to weeks), flat or slightly raised, erythematous rash that is often described by patients as burning or itching or less commonly, painful
  – Clears spontaneously over weeks
Early Localized Disease

- Erythema Migrans
  - Usually accompanied with
- Nonspecific systemic symptoms
  - Fatigue
  - Anorexia
  - HA
  - Myalgias
  - Fever

About 40% of patients have spirochetemia

“SUMMER FLU”
Early Disseminated Disease (weeks to months)

- Cutaneous Manifestations
  - EM at sites other than the original bite
- Neurologic (15% of UNTREATED patients)
  - Lymphocytic meningitis
  - Cranial nerve palsies (especially the facial nerve)
  - Radiculoneuritis
- Heart (5% of UNTREATED patients)
  - Atrioventricular block
  - Myocarditis (rarely)
Early Disseminated Cutaneous Disease
Early Disseminated Disease (weeks to months)

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Late Disease (months to years)

- Arthritis (60% of UNTREATED patients)
  - Large weight bearing joints
  - Often recurrent (70%)
- Neurologic
  - Polyneuropathy
  - Encephalomyelitis
    - True infection of the neuroaxis
    - Very rare < 1/10^6
    - More common with B. garinii
  - Encephalopathy (memory difficulties/cognitive slowing)
    - Common symptoms in individuals with inflammatory diseases
    - Common background symptoms in general population
    - THESE SYMPTOMS ARE NOT MANIFESTATIONS OF CNS LYME
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**Diagnosis**

- **Early Disease**
  - Clinical Diagnosis
  - 2-tier testing only 25% sensitive because of slow rise in IgM antibodies (1-2 weeks) and IgG antibodies (2-6 weeks)
  - Using spirochetal proteins/peptides (C6 and VlsE) known to induce a robust and early immune response can increase sensitivity to 50%

- **Late Stages**
  - CDC recommends 2-stage serologic testing
    - Screening ELISA or IFA—very sensitive but not specific (syphilis, gingivitis, LYMErix, SLE, RA etc)
      - If negative—>no further testing
      - If positive/equivocal—>confirmatory test
    - Confirmatory Western blot
Diagnosis of Late Manifestations

- Sensitivity of 2-tier testing in late Lyme disease is 100% and specificity is 99%
- “Therefore, current thinking is that all patients with objective neurologic, cardiac, or joint abnormalities associated with Lyme disease have serologic response (a + IgG western blot titer) to *B. burgdorferi*”

New Approaches to Serodiagnosis

- V1sE C6 peptide ELISA (C6 test) —measures antibodies to a protein-like sequence expressed in the sixth invariant region
  - More sensitive in early disease than 2-stage testing
  - More sensitive for European strains
- CDC, IDSA and AAN have yet to endorse the test
  - Stand alone
  - Replace Western blot
Commonly Asked Questions

• What is the explanation of an isolated positive Western blot IgM?
  – FALSE POSITIVE
• Can you get Lyme disease more than once?
  – Almost always re-infection
  – NOT relapse
• Does Lyme disease in pregnancy affect the fetus?
  – Does not predispose to congenital anomalies or fetal demise

Clues to Diagnosis

• EM occurs 3-30 days after bite--most commonly in 7-10 days
  – Early reactions that fade are due to the tick bite and are not EM
• Ticks must feed 24-36 hours to transmit organism
• Know prevalence in your area
  – East Coast 60-70% infected
  – West Coast < 5% infected
Clues to Diagnosis

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  – Early reactions that fade are due to the tick bite and are not EM
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Collection and Testing of Western Blacklegged Ticks in Sonoma County

**Tick Collections:**
Between 1985 and 2013, 6,592 *Ixodes pacificus* (western blacklegged) ticks were collected in Sonoma County:
- Adults: 3,426
- Nymphs: 1,965
- Larvae: 182

**Adult Tick Testing Results:**
1,484 adult *Ixodes pacificus* collected from Sonoma County between 1985 and 2013 were tested for *Borrelia burgdorferi* (the agent of Lyme disease), and 15 of the 328 pools of adult ticks tested positive, giving a minimum infection prevalence of 4.6%.

**Nympha Tick Testing Results:**
852 nymphal *Ixodes pacificus* collected from Sonoma County between 1985 and 2013 were tested for *Borrelia burgdorferi*, and 18 of the 217 pools of nymphal ticks tested positive, giving a minimum infection prevalence of 8.3%.

### Table 2. Recommended antimicrobial regimens for treatment of patients with Lyme disease.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dosage for adults</th>
<th>Dosage for children</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Preferred oral regimens</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amoxicillin</td>
<td>500 mg 3 times per day&lt;sup&gt;a&lt;/sup&gt;</td>
<td>50 mg/kg per day in 3 divided doses (maximum, 500 mg per dose)&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Doxycycline</td>
<td>100 mg twice per day&lt;sup&gt;c&lt;/sup&gt;</td>
<td>Not recommended for children aged &lt;8 years. For children aged ≥8 years, 4 mg/kg/day divided in 2 divided doses (maximum, 100 mg per dose)</td>
</tr>
<tr>
<td>Cefuroxime axetil</td>
<td>500 mg twice per day</td>
<td>30 mg/kg per day in 2 divided doses (maximum, 500 mg per dose)</td>
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<tr>
<td><strong>Alternative oral regimens</strong></td>
<td></td>
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</tr>
<tr>
<td>Selected macrolides&lt;sup&gt;d&lt;/sup&gt;</td>
<td>For recommended dosing regimens, see footnote d in table 3</td>
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<tr>
<td><strong>Preferred parenteral regimen</strong></td>
<td></td>
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<tr>
<td>Ceftriaxone</td>
<td>2 g intravenously once per day</td>
<td>50-75 mg/kg intravenously per day in a single dose (maximum, 2 g)</td>
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<tr>
<td><strong>Alternative parenteral regimens</strong></td>
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<td></td>
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<tr>
<td>Cefotaxime</td>
<td>2 g intravenously every 8 h&lt;sup&gt;e&lt;/sup&gt;</td>
<td>150-200 mg/kg per day intravenously in 3-4 divided doses (maximum, 6 g per day)&lt;sup&gt;f&lt;/sup&gt;</td>
</tr>
<tr>
<td>Penicillin G</td>
<td>18-24 million U per day intravenously, divided every 4 h&lt;sup&gt;g&lt;/sup&gt;</td>
<td>200,000-400,000 U/kg per day divided every 4 h&lt;sup&gt;h&lt;/sup&gt; (not to exceed 19-24 million U per day)</td>
</tr>
</tbody>
</table>
Prevention

- Light colored protective clothing with shirt tucked into pants and pants tucked into socks
- DEET
- Permethrin spray for clothes
- Tick checks with prompt removal
- Antibiotic prophylaxis—200 mg doxycycline
  - Ixodes tick; fed for 36 hours; tick infection rate >20%; antibiotics given within 72 hours of tick removal
Proper Tick Removal

- Light colored protective clothing with shirt tucked into pants and pants tucked into socks
- DEET
- Permethrin spray for clothes
- Tick checks with prompt removal
- Antibiotic prophylaxis—200 mg doxycycline
  - Ixodes tick; fed for 36 hours; tick infection rate >20%; antibiotics given within 72 hours of tick removal
Back to the Case

• A 35 yo woman is being evaluated for a 6 month h/o fatigue, arthalgias without arthritis and memory loss manifest as word-finding difficulties and forgetfulness.
• Lab tests
  – ELISA –equivocal
  – WB—positive IgM and negative IgG
• NOTE—EXPLANATION OF AN ISOLATED (+)
  Western blot IgM IS THAT IT IS A FALSE (+)
• IN LATE STAGES OF DISEASE ALMOST ALL HAVE A (+) IgG ANTIBODY TITER

New Lyme-disease Borrelia spp Identified

• Borrelia mayonii
  – Found in the upper midwestern states
  – Transmitted by Ixodes scapularis tick
• Only a few patients identified
  – More nausea and vomiting
  – Higher temperatures
  – Diffuse rash
  – High grade spirochetemia
• Detected by current 2-tier testing and C6 test
• Responds to standard Lyme disease therapy

Lancet Infect Dis, Feb 5, 2016
Controversies in Lyme Disease

• IDSA (Infectious Disease Society of America)
• Alternate view of the disease
  – LLMDs—Lyme literate physicians
  – ILADS—International Lyme and Associated Disease Society in US
    • Own set of guidelines
    • Supported by powerful patient advocacy groups
  – European equivalents
    • German Borreliosis Society
    • Dutch Lyme Association
How Far Apart Are The Views?

• IDSA
  – Clinical Manifestations
    • Skin
    • Joints (arthritis)
    • Neurologic system
    • Heart

• ILADS/LLMDs
  – Clinical Manifestations
    • Fatigue
    • Low grade fever/hot flashes
    • Night sweats
    • Sore throat
    • Swollen glands
    • Stiff neck
    • Arthralgia/stiffness/less commonly arthritis
    • Myalgia
    • Chest pain/palpitations
    • Abdominal pain/nausea
    • Diarrhea
    • Sleep disturbance
    • Poor concentration and memory
    • Instability and mood swings
    • Depression
    • Back pain
    • Blurred vision/eye pain
    • Jaw pain
    • Testicular/pelvic pain
    • Tinnitus
    • Vertigo
    • Dizziness/lightheadedness
    • Headaches
    • Cranial nerve disturbances

How Far Apart Are The Views?

• IDSA
  – Diagnosis
    • 2-tier testing
    • 1983 study using “crude” (early) assay 94% had a positive test
    • 2008 article by Steere 99% with late disease had positive test

• ILADS/LLMDs
  – Diagnosis
    • Since there is no definitive test for Lyme disease, laboratory results should not be used to exclude an individual treatment
    • Lyme disease is a clinical diagnosis and tests should be used to support rather than supersede the physicians judgment
    • Diagnosis of Lyme by 2-tier confirmation fails to detect up to 90% of cases
How Far Apart Are The Views?

- **IDSA**
  - Therapy
    - Longest duration 28 days
    - May need to re-treat some with persistent arthritis

- **ILADS/LLMDs**
  - Therapy
    - Rather than an arbitrary 30-day treatment course, the patients clinical response should guide duration of therapy
    - Combination and sequential therapy that can last months

How Contentious Is It?

very
Antiscience and ethical concerns associated with advocacy of Lyme disease


Lancet Infect Dis 2011;11:713-719

Antiscience and Ethical Concerns

- Antiscience groups and pseudoscientific practitioners
- Using unvalidated laboratory tests
- Various specialty laboratories in CA and KS that have been investigated and fined
- List current and former ILADS officers sanctioned by state medical boards or reprimanded by federal agencies
Unvalidated Laboratory Tests by “Specialty Laboratories”

• Urine PCR for tick-borne pathogens

• Record of 11 pathogens from a single patient
  – B. burgdorferi, B. miyamotoi, B. recurrentis, A. phagocytophilum, B microti, B. divergens, B. duncani, B. bacilliformis, B. henselae, B. quintana and E. chaffeensis
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• Current political climate these positive results

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ALTERNATIVE FACTS
Antiscience and Ethical Concerns

- Antiscience groups and pseudoscientific practitioners
- Using unvalidated laboratory tests
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<th>IOEKEN IGM RESULT</th>
<th>CDC/ATS RESULT</th>
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<td>16 kDa</td>
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<td><strong>23-25 kDa</strong></td>
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<td>28 kDa</td>
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<td><strong>30 kDa</strong></td>
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<td><strong>31 kDa</strong></td>
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<td><strong>34 kDa</strong></td>
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<td><strong>39 kDa</strong></td>
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<td><strong>41 kDa</strong></td>
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<td>58 kDa</td>
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<td>66 kDa</td>
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<td><strong>83-93 kDa</strong></td>
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Antiscience and Ethical Concerns

• Antiscience groups and pseudoscientific practitioners
• Using unvalidated laboratory tests
• Various specialty laboratories in CA and KS that have been investigated and fined
• List current and former ILADS officers sanctioned by state medical boards or reprimanded by federal agencies
Prolonged use of antibiotics—months to years
Three patients with PICC line sepsis
Using “unconventional therapy”—IV garlic

“Lyme Doctor Protection Act”

• A law signed by Governor Andrew Cuomo on December 15, 2014
• The law prohibits the state board of medicine from investigating complaints of substandard care “based solely on their recommendation or provision of treatment modality that is currently not universally accepted by the medical profession.”
• In NY, “unconventional therapy” is now protected under law
Letters

RESEARCH LETTER

Neoplasms Misdiagnosed as “Chronic Lyme Disease”

JAMA Internal Medicine January 2015 p 132

CDC Website

Pituitary tumor misdiagnosed as CLD for 3 years
Complications of Treatment of “Chronic Lyme disease”  
(MMWR June 16, 2017)

<table>
<thead>
<tr>
<th>Patient</th>
<th>Therapy</th>
<th>Complication</th>
<th>Outcome</th>
</tr>
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<tbody>
<tr>
<td>A—female late 30’s</td>
<td>IV abx</td>
<td>Sepsis/septic shock</td>
<td>Died</td>
</tr>
<tr>
<td>B—adolescent female</td>
<td>IV and oral abx for 5 months</td>
<td>Septic shock d/t acinetobacter</td>
<td>Survived after prolonged ICU stay</td>
</tr>
<tr>
<td>C—female late 40’s</td>
<td>IV and oral abx + anti-parasitic</td>
<td>Sepsis/osteomyelitis/discitis d/t pseudomonas</td>
<td>Recovered</td>
</tr>
<tr>
<td>D—female in 50’s</td>
<td>IV and oral abx + anti-viral, anti-fungal and anti-parasitic for 7 months</td>
<td>Recurrent C difficile</td>
<td>Died from ALS</td>
</tr>
<tr>
<td>E—female in 60’s</td>
<td>IV immunoglobulins q 3 weeks for &gt;10 years</td>
<td>MSSA osteomyelitis and paraspinous abscess requiring surgery</td>
<td>Survived</td>
</tr>
</tbody>
</table>

Counterpoint

- World Wide Lyme Rally & Protest May 10, 2013 Union Square, NYC—comments by Dr. Kenneth Liegner
“Chronic Lyme disease does not exist”

There are at least four possibilities to explain why a person might hold this view:

– They can be “dumb as bags of rocks”
Counterpoint

• “Chronic Lyme disease does not exist”
• There are at least four possibilities to explain why a person might hold this view:
  – They can be “dumb as bags of rocks”
  – They can be character-disordered, with exceeding rigid thinking, impenetrable, circular logic
Counterpoint

• “Chronic Lyme disease does not exist”
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  – They can be “dumb as bags of rocks”
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  – They can be corrupt
  – They can be sociopaths

• One thing is for damn sure:
Counterpoint

• “Chronic Lyme disease does not exist”
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  – They can be character-disordered, with exceeding rigid thinking, impenetrable, circular logic
  – They can be corrupt
  – They can be sociopaths
• One thing is for damn sure: they are truly lousy clinicians

How Contentious Is It?

The Clinical Assessment, Treatment, and Prevention of Lyme Disease, Human Granulocytic Anaplasmosis, and Babesiosis: Clinical Practice Guidelines by the Infectious Diseases Society of America

Gary P. Wormser,1 Raymond J. Dattwyler, Eugenia D. Shapiro,2 John J. Halperin,3,4 Allen C. Steere,3 Mark S. Klempner,5 Peter J. Krause,2 Johan S. Bakken,2 Franc Steere,2 Gerald Steere,2 Linda Bockenstedt,1 Durland Fish,4 J. Stephen Dumler,10 and Robert B. Nadelman1

Clinical Infectious Diseases 2006;43:1089-1134
How Contentious Is It?

Shortly after the guidelines were published, then AG Blumenthal sued the IDSA saying the guidelines “severely constrict choices and legitimate diagnosis and treatment options of patients”.

In addition, he accused the IDSA:
1. Several panelist had conflicts of interest
2. Panel refused to consider information about CLD
3. Refused to appoint panelists with divergent views on CLD

Law Suit Against IDSA

- Blumenthal ended suit in 2008
- Blumenthal & IDSA agreed to appoint a new committee vetted by both sides to review the data in the recommendations
- All day open public hearing to offer a forum for alternative views of the diagnosis and treatment of Lyme disease
  - 3 from Lyme advocacy groups
  - 4 ILADS/LLMDs
The Final Report--2010

• The recommendations in the 2006 Guidelines were evidence-based and of the highest scientific quality-- all recommendations should stand.
• The approach to diagnosis and therapy supported by of the International Lyme and Associated Disease Society (ILADS/LLMDs) was not evidence-based and should not alter the published recommendations.

Two Common Scenarios

• Scenario 1
  – Patient has documented Lyme disease and after therapy continues to have nonspecific symptoms
• Post-Lyme disease Syndrome (<10%)
  – Antibiotics – multiple RDBPCS
    • 3mos of abx v placebo —> no difference in symptoms
  – Xenodiagnosis
    • Unable to infect laboratory strains of Ixodes ticks
  – Immunology
    • T_{H}^{17} response with high levels of IL-23 v usual T_{H}^{1} response
Two Common Scenarios

• Scenario 2
  – Patient has nonspecific symptoms and no evidence of exposure to Borrelia burgdorferi i.e. antibody tests are negative
• This is where most of the “philosophical divide” occurs
  – They may have some underlying infection...BUT
    • I don’t think it is Lyme disease
    • I have seen no evidence that the symptoms respond to antibiotics

Some Observations

• Spirochetal diseases that affect humans
  – Relapsing fever (Borrelia recurrentis and other Borrelia spp)
  – Leptospirosis (Leptospira species)
  – Syphilis (Treponema pallidum)
  – Lyme disease (Borrelia species)
• Diagnosed with antibody studies &/or direct visualization
  – Relapsing fever—70% by visualization
  – Leptospirosis—55% by serology
  – Syphilis—95%-100% by serology
• Duration of therapy
  – Relapsing fever—single dose to 10 days
  – Leptospirosis—up to 7 days for severe disease
  – Syphilis—depends on stage of disease; neurosyphilis 10-14 days
Some Questions

• With all of the patients with “chronic Lyme disease” treated by LLMDs with long term antibiotics, why has there never been a randomized, double-blinded controlled study to see if antibiotics are any more effective than placebo?

Poly-ticks: Blue State versus Red State for Lyme disease-2004
Poly-ticks: Blue State versus Red State for Lyme disease-2004

Bush/Cheney vs Kerry/Edwards

Lyme Disease/Ixodes tick

Southern Tick-Associated Rash Illness—STARI/Amblyomma americanum (Lone Star Tick)